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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In re application of:

Champion, Mary J.

) Group Art Unit: 1615

)

Serial No. 10/576,803

)

Examiner: Isis Ghali

)

Filed: April 21, 2006

)

)

For: SYSTEMS AND METHODS FOR

)

TREATING HOT FLASHES

)

ASSOCIATED WITH MENOPAUSE)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on or before

Date

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF MARY J. CHAMPION
UNDER 37 CFR 1.132

I, Mary J. Champion, declare as follows:

1. That I am the sole inventor in the above-identified application, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/563,237, filed April 16, 2004.

2. That after the filing of the above-noted provisional application, I conducted extensive research on the internet looking for prospective licensees for my invention as set forth in the above-noted provisional application. Among the companies I researched was Kobayashi Healthcare, Inc (hereinafter referred to as "Kobayashi").

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3. During this period of time after April 16, 2004, I noted that Kobayashi did sell/advertise cooling patches for treatment of fevers, migraines, headaches, sprains, arthritis, toothaches, heat discomfort, overexertion and overheating. For example, Attachment A, attached hereto and made a part hereof, is a copy of portions of Kobayashi's website for their "BeKooool" cool gel sheets product, which website portions I printed out on May 18, 2004. Importantly, the Kobayashi website did not show, mention or otherwise even suggest that this cool gel sheets product were, or even could be, used to treat hot flashes associated with menopause.

4. In May, 2004, after the filing of the above-noted provisional application, I contacted Kobayashi to inquire about their possible interest in my invention. I generally discussed my invention with a Mr. Ohara, an employee of Kobayashi, who I understand was very familiar with Kobayashi's BeKooool cool gel sheets product. Mr. Ohara declined to sign a Non-disclosure agreement that I had proposed. Mr. Ohara did not inform me that Kobayashi was, at that time in May, 2004, marketing/selling, or even contemplating marketing/selling, any product for treating hot flashes associated with menopause.

5. In June, 2004, Kobayashi informed me that they were not interested in my invention.

6. Periodically during the remainder of 2004 and the first half of 2005, I checked Kobayashi's website and confirmed that no showing or other disclosure was made on this website that this "Be Kooool" product, or any other Kobayashi product, was, or even could be, used to treat hot flashes. During this

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time period, I did not see any advertising, packaging or any other material for any "BeKool for Adults" product referring to hot flashes.

7. Based on my own research on the internet and since neither Kobayashi nor anyone else identified to me any cooling product to treat hot flashes associate with menopause, no cooling product from Kobayashi for the treatment of such hot flashes was marketed/sold before or during 2004, and during the first half of 2005.

8. In July 2005, I first became aware of Kobayashi's new product, packaging and advertisement for "BeKool Hot Flash". Attachment B, a copy of the advertisement for "BeKool Hot Flash" I first became aware of on July 18, 2005, is attached hereto and is made part hereof. I promptly contacted Kobayashi to discuss this development. In response, Kobayashi provided me with a power point presentation of an unpublished, half completed Product Concept Test which bears a date in 2003. I have no way of verifying that this Product Concept Test was conducted at all, let alone in 2003, particularly since Kobayashi's product "BeKool Hot Flash" was not marketed/sold until July, 2005. Moreover, this Product Concept Test does not disclose my invention.

9. On December 3, 2007, an Office Action in the above-identified application was mailed by the Examiner, for the first time, citing the "BeKool Hot Flash" product against the claims of the above-identified application. Specifically, the "BeKool Hot Flash" product was described in a pamphlet, shown in Attachment C attached hereto and made a part hereof, which was provided by the Examiner in form PTO-892, which accompanied the

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December 3, 2007 Office Action. This pamphlet is undated. A part of this pamphlet is similar to the product, packaging and advertisement for "Be Kooool Hot Flash" (Attachment B) which is dated July, 2005. The only date on the pamphlet received from the Patent and Trademark Office is 11/29/07. Thus, the earliest date that I am aware of that any portion of the pamphlet was published was July, 2005, well after the filing date of the above-noted provisional application.

10. In view of the above, the "BeKooool Hot Flash" pamphlet being relied on by the Examiner to reject the claims in the above-identified application is not prior art against these claims, each of which is fully supported by the above-noted provisional application, filed April 16, 2004.

11. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the applications or any patent issuing thereon.

Signed this 30 day of June, 2008.


MARY J. CHAMPION



Soft gel cooling sheets for adults and children

The cool that soothes fevers, migraines, headaches,
sprains, arthritis, toothaches, and heat discomfort.
Immediate cooling relief for hours.

Learn About Be Koool

Where To Purchase Be Koool

Kobayashi Healthcare

What's New

Kobayashi Worldwide

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Be Koool for Adults
Whenever you'd use a cold compress or towel, use Be Koool instead. There's no drip, no mess, and the soothing relief lasts for up to four hours. The soft gel sheet stays in place, so you can even wear it to keep your cool during jogging or other activities.



Be Koool for children
Specially sized Be Koool for Children means you'll never have to keep changing mossy towels that lose their cool even faster than they fall off a fussy child's forehead. Be Koool stays cool for six hours and stays put, so you and your child will both feel better. Perfect for those overheated days and nights of summer.



TELL ME MORE ►

ATTACHMENT A



Always there when you need it.



Learn About Be Koool

Where To Purchase Be Koool

Kobayashi Healthcare

What's New

Kobayashi Worldwide

Contact Us

< Home

- Ready to use, requires no refrigeration.
- Sheets may be cut to fit specific parts of the body.
- Safe to use with medication.
- Doctor recommended.
- The convenient way to provide soothing, cooling relief for fever, migraine, headache, overexertion, and overheating.
- Ideal for use before, during, and after workouts and strenuous activity.

ATTACHMENT A

Be Kool Hot Flash Gel Sheets 6 ea



[see larger photo](#)

suggested: \$5.99

our price: \$5.69

save 5%

quantity:

☒ Add Be Kool Hot Flash Gel Sheets to your

availability: temporarily out of stock - will ship in 1-2 week

(Shopping i

▶ [see all products in cold packs](#)

▶ [visit our Be Kool Store](#)

▶ [view package details](#)

▶ be the first to [write a review](#)

▶ add item to **your list™**

▶ [e-mail a friend](#) about this item

package details

For Immediate Cooling Relief

Ready To Use - No Color - No Fragrance - Self Adhesive - Easy to Carry

Contains 6 Soft Gel Sheets - Each 2" x 4 1/4"

Features:

- Be Kool® Hot Flash gel sheets provide immediate cooling relief in a convenient disposable product. They need no refrigeration, are portable, and ready to use anywhere and anytime you have Hot Flash Discomfort.
- Be Kool® Hot Flash gel sheets safely and gently adhere to your skin.
- Be Kool® Hot Flash gel sheets are sized to fit your neck or forehead and offer just the right amount of cooling to maximize your comfort
- The cooling effect of each sheet last up to 5 hours. Be Kool® Hot Flash gel sheets are safe to use with medication taken internally.

Directions:

Use on Neck, Forehead, Chest, Arm - Whenever you feel the need for cooling relief.

- Cut open pouch and remove one cooling gel sheet
- Remove transparent film from back of gel sheet and discard. Place gel sheet on skin.
- If desired, gel sheet may be cut to suitable size with scissors.
- Store unused gel sheet in the foil pound to prevent drying. Reseal pouch by tightly folding the

7/18/2005

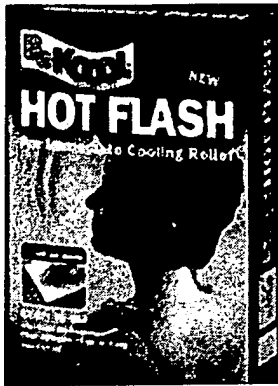
ATTACHMENT B

pouch twice along the dotted lines.

- Store in a cool dry place. May even be store in refrigerator for extra cooling. Do not store in freezer.
- For sanitary reasons, use each sheet only once and discard after use.

Warnings:

- Keep this product out of reach of children.
- Use only as directed. For external use only. If excessive redness, irritation, burning or discomfort of the skin develops, discontinue use and consult your physician immediately.
- Do not apply to wounds or to Irritated, damaged, sunburned or very sensitive skin.
- Do not allow the product to enter or block nose or mouth
- This product should be used only under strict supervision when applied to children, the physically handicapped/disable, or those who can not apply the product themselves.
- Consult your physician if this product does not help relieve your hot flash discomfort as the gel sheets do not contain medication.
- The cooling gel sheet will not adhere if the skin is wet or if the gel sheet comes into contact with hair, eyebrows or clothing.



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Be Kooool Hot Flash is a proud supporter of The American Menopause Foundation, Inc. (AMF), the only independent, not-for-profit health organization dedicated to aiding research, providing support, education and assistance on all issues concerning menopause.



American Menopause Foundation
[CLICK HERE](#)

[CLICK HERE TO LEARN MORE
ABOUT HOT FLASHES](#)



KOBAYASHI Kobayashi Healthcare, LLC
[CLICK HERE](#)

ATTACHMENT C

Be Kooool
**HOT
FLASH**



ATTACHMENT C

	Use Anytime	Discreet	Not Ingested	Portable	Works 5 Hours	Side Effects
Be Kool	Yes	Yes	Yes	Yes	Yes	No
Remove Clothes or Covers	No	No	Yes	Yes	Yes	No
Adjust Room Temperature	No	No	Yes	No	Yes	No
HRT	Yes	Yes	Yes	Yes	Yes	Possible
Ice Packs	No	No	Yes	Yes	No	No
Herbs or Vitamins	Yes	Yes	No	Yes	Varies	Possible

ATTACHMENT C